REMARKS

Status of the Claims and Amendment

Claims 1, 3, 4, 6-8, and 12 have been amended. Claims 1-28 are all the claims pending in this application. Claims 17-28 are withdrawn from consideration as being directed to a non-elected invention. Claims 1-16 are rejected.

Claims 1 and 12 have been amended without prejudice to only refer to elected "SEQ ID NO:11" and to replace "in which one or several nucleotide(s) is/are deleted, substituted, inserted and/or added" with "having 80% or more homology". Support for the amendments to claims 1 and 12 may be found throughout the specification as filed, for example, Example 3 at pages 75-79.

Claim 3 has been amended without prejudice to only refer to elected "SEQ ID NO:1" and to clarify that the "DNA which hybridizes to the nucleotide sequence that is entirely complementary to SEQ ID NO:1 under stringent conditions and encodes a protein having α1,6-fucosyltransferase activity." Support for the amendments to claim 3 may be found throughout the specification as filed, and at, for example, page 8, lines 9-10. Applicants note that it would have been apparent and technically logical to one of ordinary skill in the art possessing technical knowledge of the art and from reading the specification, that Applicants' intended to claim a DNA that hybridizes to an entirely complementary nucleotide sequence of SEQ ID NO:1 and encodes α1,6-fucosyltransferase activity.

Claim 4 has been amended without prejudice to only refer to elected "SEQ ID NO:5". Similarly, claim 6 has been amended without prejudice to only refer to elected "*Lens culinaris* lectin", claim 7 has been amended to only refer to elected "animal cell", and claim 8 has been amended to refer to only elected "CHO cell derived from Chinese hamster ovary tissue."

No new matter is added.

Claim of Priority

Applicants thank the Examiner for acknowledging Applicants' claim to foreign priority and receipt of a certified copy of the priority document, JP 2003-350167 filed October 9, 2003 from the International Bureau.

Information Disclosure Statements

Applicants thank the Examiner for returning signed and initialed copies of the PTO Forms SB/08 that accompanied the Information Disclosure Statements filed April 10, 2006 and November 9, 2006.

Allowable Subject Matter

On page 4 of the Office Action, the Examiner indicates that SEQ ID NO. 11 appears free of the prior art searched and of record.

Response to Claim Rejections Under 35 U.S.C. § 112

Claims 1-16 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly not satisfying the written description requirement.

Specifically, the Office Action appears to assert that the specification does not adequately describe the broad genus of variant compounds comprising any nucleotide deletions, substitutions, insertions or additions of SEQ ID NO. 11, in which the expression of α1,6-fucosyltransferase is suppressed. That is, the Office Action asserts that it is unclear which deletions, insertions, additions or substitutions to SEQ ID NO. 11 would provide for the suppression of any or of all four α1,6-fucosyltransferases claimed.

Therefore, the Office Action appears to conclude that because the scope of the claim encompasses a genus of structural variants, the specification does not provide sufficient

description of a representative number of species to show Applicants had possession of the claimed genus.

In response, Applicants assert that the BPAI has noted that "[t]he written description requirement . . . does not require a description of the complete structure of every species [within] a chemical genus," *Ex parte Bandman*, No. 2004-2319, slip op. at 3 (B.P.A.I. January 6, 2005).

Nevertheless, and solely to advance prosecution of the present application, claims 1 and 12 , have been amended to remove "in which one or several nucleotide(s) is/are deleted, substituted, inserted and/or added" and recite "an RNA consisting of a nucleotide sequence having 80% or more homology to the nucleotide sequence of SEQ ID NO:11 and having activity of suppressing the function of an enzyme relating to the modification of a sugar chain in which 1-position of fucose is bound to 6-position of N-acetylglucosamine in the reducing end through α-bond in a complex type N-glycoside-linked sugar chain." Applicants note that such an amendment meets the written description requirement and is commensurate with the revised PTO Guidelines (published March 25, 2008) which indicate that the written description requirements under 112, first paragraph are satisfied for a nucleotide that encodes a polypeptide with at least 85% amino acid sequence identity to a particular sequence even when only that particular sequence (a single species) is disclosed (see Example 11 of revised PTO Guidelines). Moreover, procedures for making these variants are conventional in the art.

Accordingly, the teachings of the specification when combined with the knowledge of one of ordinary skill in the art are sufficient to comply with the written description requirement. One of ordinary skill in the art would understand from reading the specification that the structure of the enzyme relating to the modification of a sugar chain in which 1-position of fucose is bound to 6-position of N-acetylglucosamine in the reducing end through α-bond in a complex

type N-glycoside-linked sugar chain has been known in the art since 1976 (see page 2, lines 30-36 of the specification). Also, the presently claimed RNA comprising the nucleotide sequence of SEQ ID NO:11 is described at pages 15-19 of the specification, as well as disclosure of making the claimed RNA and functional variants of the claimed RNA (see page 20, 1st full paragraph, pages 34-35, Examples 1 to 3 at pages 64-79), so that one of ordinary skill in the art would have understood that Applicants were in full possession of the other species or homologs encompassed by the claimed RNA. For instance, the specification discloses that a homology search was performed on the target sequences represented by SEQ ID NOs:9-18 and found to correspond to respective mouse, rat and human FUT8 sequences (see page 72, lines 4-27 of the specification). Also, Examples 2 and 3 and Table 2 shows the activity of suppressing the function of an enzyme relating to the modification of a sugar chain in which 1-position of fucose is bound to 6-position of N-acetylglucosamine in the reducing end through α-bond in a complex type N-glycoside-linked sugar chain by the siRNA and siRNA variants of the claimed invention. Accordingly, the specification and claims provide an identification of common characteristics of the claimed polypeptide, e.g., structure, physical, and/or chemical, characteristics coupled with known or disclosed correlation between function and structure. Further, it would be within common technical practice for one of ordinary skill in the art to perform a homology search or alignment to determine the degree of similarity between the sequences disclosed, and to surmise from the homology search or alignment, the regions of conserved amino acids that are important for function without undue experimentation. One of ordinary skill in the art would understand and surmise based on common technical knowledge and common sense, e.g., determination of homology in the nucleotide sequence based on a BLAST search algorithm, and the disclosure in the specification, that Applicants had possession of the presently claimed RNA consisting of the

nucleotide sequence having 80% or more homology with the nucleotide sequence of SEQ ID NO:11 and having activity of suppressing the function of an enzyme relating to the modification of a sugar chain in which 1-position of fucose is bound to 6-position of N-acetylglucosamine in the reducing end through α-bond in a complex type N-glycoside-linked sugar chain.

Therefore, the siRNA of the claimed invention are fully disclosed in the present specification, and share common structural features required for having the activity of suppressing the function of an enzyme relating to the modification of a sugar chain in which 1-position of fucose is bound to 6-position of N-acetylglucosamine in the reducing end through α-bond in a complex type N-glycoside-linked sugar chain, i.e., at least 80% homology with the nucleotide sequence of SEQ ID NO:11. For at least the reasons discussed above, one of ordinary skill in the art possessing common technical knowledge would understand from reading the specification, that Applicants were in possession of the presently claimed invention at the time the invention was made.

Furthermore, claims 1 and 12 have been amended without prejudice to only refer to elected SEQ ID NO:11. Claim 3 has also be amended without prejudice to only refer to elected SEQ ID NO:1, claim 4 to only refer to elected SEQ ID NO:5, claim 6 to only refer to *Lens culinaris* lectin, claim 7 to only refer to an animal cell, and claim 8 to only refer to CHO cells.

Reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph, is respectfully requested.

Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

/Tu A. Phan/

Tu A. Phan, Ph.D.
Registration No. 59,392

SUGHRUE MION, PLLC
Telephone: (202) 293-7060
Facsimile: (202) 293-7860
WASHINGTON DC SUGHRUE/265550
65565
CUSTOMER NUMBER

Date: January 29, 2010